Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IL05/000163

International filing date: 09 February 2005 (09.02.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/572,283
Filing date: 17 May 2004 (17.05.2004)

Date of receipt at the International Bureau: 14 April 2005 (14.04.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

PCT/IL2005/000163
06 APR 2005

PA 1285807

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

February 24, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: *60/572,283*
FILING DATE: *May 17, 2004*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

N. WILLIAMS
Certifying Officer

Please type a plus sign (+) inside this box → [+]

PTO/SB/16 (8-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

21861 U.S.PTO

22264 U.S.PTO 60/572283 051704

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Simcha	MILO	6a Noga Street Haifa Israel

[X] *Additional inventors are being named on the 1 separately numbered sheets attached hereto.*

TITLE OF THE INVENTION (280 characters max)

ULTRASONIC SYSTEMS AND TRANSDUCER ASSEMBLIES

CORRESPONDENCE ADDRESS

Direct all correspondence to:

[ ] Customer Number [ ] → *Place Customer Number Bar Code Label here*

OR *Type Customer Number here*

[X] Firm or Individual Name	ABELMAN, FRAYNE & SCHWAB Attorneys at Law				
Address	150 East 42nd Street				
Address	New York, New York 10017				
City		State		Zip	
Country	U.S.A.	Telephone	(212) 949-9022	Fax	(212) 949-9190

ENCLOSED APPLICATION PARTS (*check all that apply*)

[X] Specification (includes drawings) *Number of Pages* 27 [ ] CD(s), Number

[ ] Drawing(s) *Number of sheets* [ ] Other (specify)

[ ] Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

[X] Applicant claims small entity status. See 37 CFR 1.27.

[X] A check or money order is enclosed to cover the filing fees

[X] The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 01-0035

[ ] Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): $80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No.

[ ] Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Jay S. Cinamon

TYPED or PRINTED NAME Jay S. Cinamon

TELEPHONE (212) 949-9022

Date May 17, 2004

REGISTRATION NO. (*if appropriate*) 24,156

Docket Number: 206,543

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The informati provisional application. Confidentiality is governed by 35 U.S.C. 122 an to complete, including gathering, preparing, and submitting the complet depending upon the individual case. Any comments on the amount of t reducing this burden should be sent to the Chief Information Officer, U.S Commerce, Alexandria, VA 22313-1450. DO NOT SEND FEES OR CO Stop Provisional Application, Assistant Commissioner for Patents Alexa

"EXPRESS MAIL" Label No.: ET537590349US Date of Deposited: May 17, 2004 This correspondence is being Deposited with the United States. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

PROVISIONAL APPLICATION COVER SHEET
Additional Page

PTO/SB/16 (8-00)
Approved for use through 10/31/2002. OMB 0651- 0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Docket Number	206,543	Type a plus sign (+) inside this box →	+

INVENTOR(S) APPLICANT(S)

Given Name (first and middle (if any)	Family or Surname	Residence (City and either State or Foreign Country)
Nathan	SELA	73 Shimon Street Modiin Street
Michael	KARDOSH	4 Ha-Keshet Street Kiryat Ono Israel

Number 2 of 2

Ultrasonic systems and transducer assemblies

Invention #1 – Ultrasonic system and transducer assembly

Introduction

Ultrasound energy for therapeutic applications is used in various medical scenarios such as destroying stones in the urinary system using sound shock waves (Lithotripter), high intensity focused ultrasound for ablation of malignant and benign tumors, ultrasound for acoustic management of embolism etc.

Any application, which involves the need to generate acoustic energy extra-corporeally and delivering this energy into the living body, for any medical diagnostic or therapeutic purpose, must accommodate several conditions of technological nature:

1. Acoustic matching for efficient delivery of acoustic energy from the transducer to the body, taking into account an arbitrary shape of the body
2. Avoiding heating of the transducer during operation which may influence its efficiency or even lead to its permanent malfunction (this condition is relevant mainly to power ultrasound applications)
3. Avoiding heating of insonated tissue, especially skin which is prone to heating by acoustic energy
4. Eliminating acoustic obstacles, such as bubbles, from the path of acoustic energy between the transducer and the target body

Description of the invention

The invention disclosed in this document is a system for delivery of ultrasonic energy into the body or more specifically a transducer assembly, designed to address the technological problems described above. A general schematic figure of the disclosed transducer assembly is given in Figure 1 below:

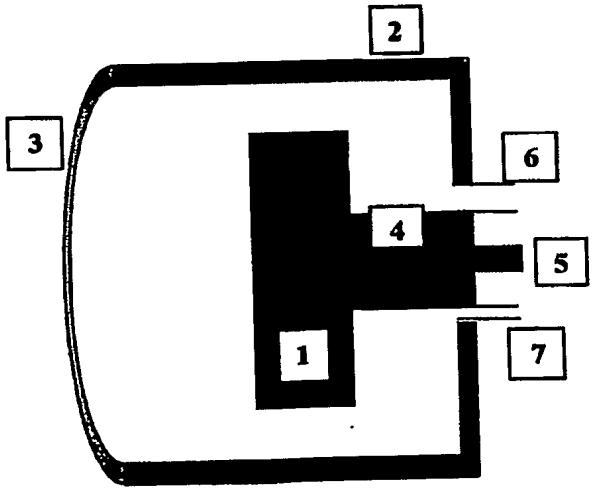

Figure 1 – A general schematic view of the transducer assembly

Figure 1 depicts the disclosed assembly which in based on an ultrasonic transducer **1**, generally but not necessarily a power transducer, which is fully enclosed within a housing **2**, made from any solid material such as but not limited to plastics i.e. Perspex, Polycarbonate, Teflon, Acculon or metals i.e. Aluminum or Steel or any flexible material. The frontal part of the housing **3** is made from a thin flexible, acoustically transparent membrane such as but not limited to Latex, Polyurethane, Polyethylene, etc. The transducer is fixed within the housing on a fixed mount **4**. The power cable of the transducer **5** is integrated to the housing **2** such that electrical energy may be delivered to the transducer from external source via this power cable **5**. The housing is hermetically sealed except for two ports **6** and **7**. Port **6** is an inlet port connected to a liquid pump such as to allow flow of liquid into the housing and port **7** is an outlet port allowing liquid to flow from the housing back to the pump. The ports may be designed in such a way that the resistance to flow through port **7** is larger than the resistance to flow through port **6** so that residual positive pressure will be maintained within the housing which will inflate the flexible layer **3** and press it against the body. The difference in flow resistance can be obtained for example by making the outlet port **7** narrower that inlet port **6.** The liquid used in this device can be water, degassed water or any other coolant used in the industry.

Figure 2 below depicts in block diagram of the complete system connection of the device depicted in Figure 1 above to peripheral components:

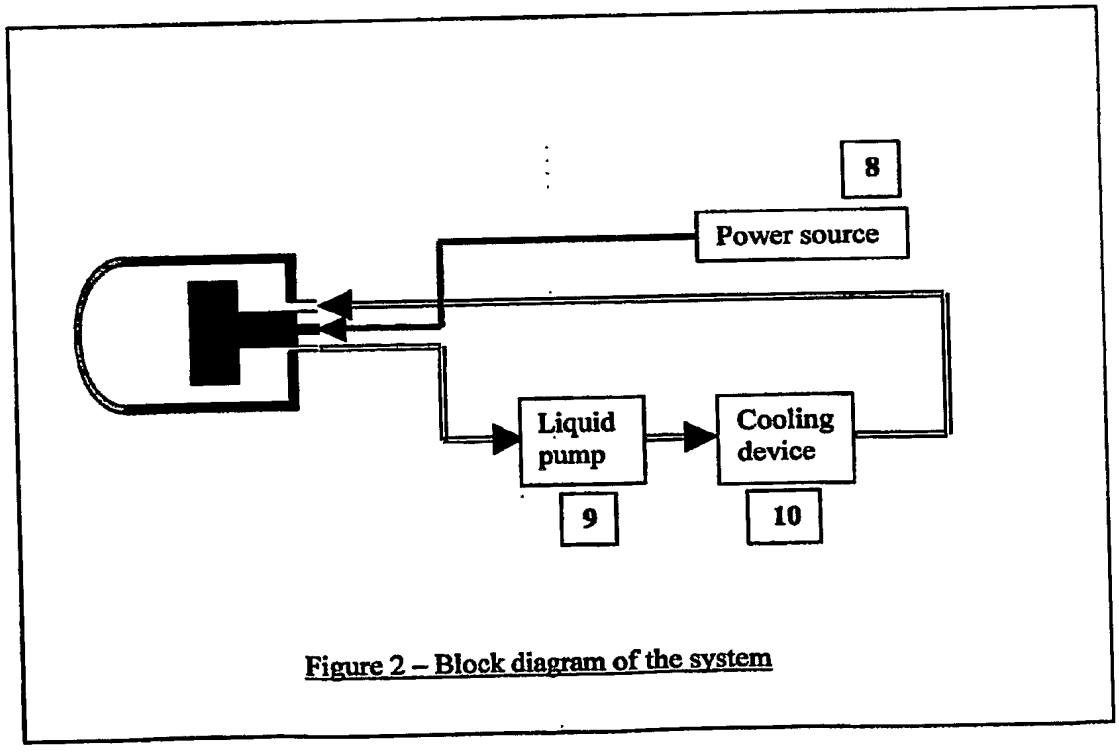

Figure 2 – Block diagram of the system

As is depicted in Figure 2 above, the full system contains two circuits – the first circuit is electrical which provides electrical power generated by the power source **8** and delivered to the transducer to be converted to acoustical power. The second circuit is based on a pump **9** driving the liquid into the housing. A cooling device **10** such as, but not limited to, a small refrigerating unit is connected in series and cools the temperature of the liquid down to a controlled temperature prior to driving the liquid back into the housing.

The invention disclosed in this document possesses some unique attributes

1. Acoustical coupling between the transducer and the treated organ is ensured by continuous liquid path from the surface of the transducer to the flexible membrane
2. Cooling the transducer which is fully immersed in liquid on one side and the surface of the organ (usually, skin) on the other side by the liquid which serves also as a coolant
3. Dynamic inflation of the flexible layer and pressing it against the surface of the skin by virtue of the positive residual liquid pressure within the housing, ensures good coupling even to organ with peculiar surface structure
4. Rapid liquid flow through the housing removes air bubbles which may disperse the acoustic energy within the housing

It should be noted that the technical description provided above is merely a single realization of the presented invention. There are numerous alternatives to realize this invention which may be suggested by an average person skilled in the art, such as

- Different mounting of the transducer within the housing
- Different materials for housing, flexible layer or circulating liquid
- Different method for generating residual positive pressure inside the housing
- Different cooling devices

All such changes and others, which may be suggested by an average person skilled in the art, should be considered as obvious and clearly falling within the scope of the present invention.

Invention #2 – Ultrasonic system and disposable sterile transducer assembly

Introduction

In a previous provisional application, no 60/544,459 filed on February 12, 2004, by the same inventors, a method and system for deflecting embolic flow in the aortic arch has been disclosed. The main application of the above mentioned invention is to protect the brain of a patient undergoing cardiac surgical procedure, such as coronary bypass surgery or heart valve replacement surgery, from emboli created throughout the course of the surgical procedure and endanger the neurological function of the patient. In the above-mentioned provisional application, several methods of fixation of the transducer within the chest cavity were disclosed and discussed.

In order for such a device to be applicable for use in cardiac surgery, the transducer and its surrounding support system must comply with the technical and clinical need as well as to surgical theater regulations. Such as:

1. Full sterility of system components residing in the surgical field without compromise even under fault (spillage of coolant into the body of the patient)
2. Allow simple and fast attachment of the transducer to the aorta such that the location of the transducer relative to the aorta will not change under movement of the aorta during the surgery
3. Acoustical matching between the transducer and the insonated tissue (aorta etc) with compliance to irregular tissue surface structure
4. Avoid contacting the aorta with hard elements in order to avoid embolization from detached aortic plaque
5. Provide cooling to the transducer in order to keep it operating within its normal operating regime
6. Provide cooling to the surface of the insonated tissue in order to avoid potential heating by the absorbed ultrasonic energy

Description of the invention

The invention disclosed below is a system and transducer assembly for delivery of ultrasonic energy to any part within the human body during surgery and more specifically for delivery of ultrasonic energy to the aortic arch during cardiac surgery for the purpose of re-routing embolic flow in the aortic arch and avoiding its passage into the cerebral vessels. The system comprises an external component (non-disposable) and a disposable component which is simple to deploy in association with the aortic arch, amenable for fast and simple sterilization, does not compromise sterilization requirements even if faulty and provides soft and efficient acoustic coupling to the insonated tissue, e.g. the aorta.

A general schematic figure of the disposable transducer component is given in Figure 3 below (it should be noted that Figure 3 is not to scale).

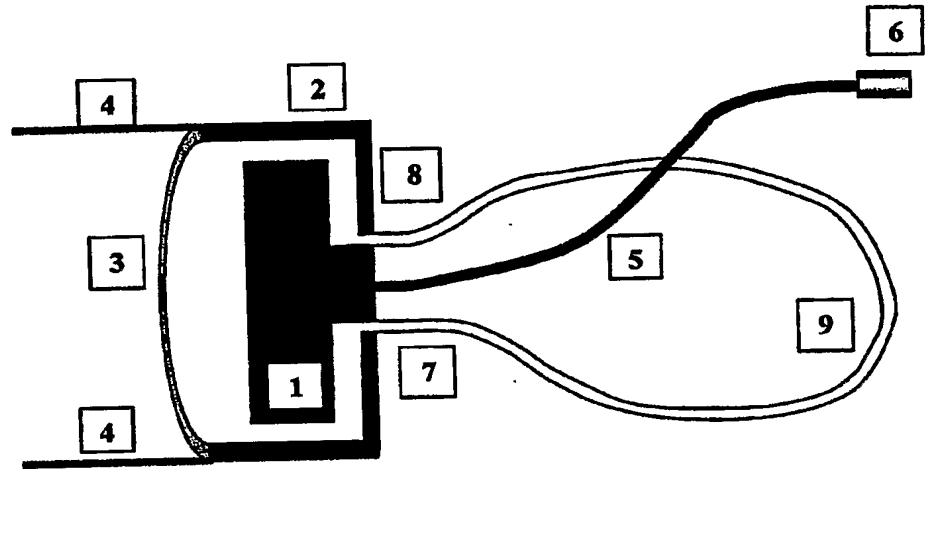

Figure 3 – General schematic view of the disposable component

Figure 3 depicts the disclosed system which in based on an ultrasonic transducer **1**, generally but not necessarily a power transducer, which is fully encapsulated within a hollow housing **2**, made from any solid material such as but not limited to plastics i.e. Perspex, Polycarbonate, Teflon, Akulon or metals i.e. Aluminum or Steel, or a flexible material. The frontal side of the housing **3** is a membrane made from a thin flexible, acoustically transparent material such as but not limited to Latex, Polyurethane, Polyethylene, etc. Attached to the housing is/are one or two (or more) wires **4** whose shape may be easily deformed by hand, such as made from a "soft metal" such as Copper. If the wire is made from a non-bio-compatible material it may be enveloped in a biologically inert soft material such as Silicone. The wires serve to attach the transducer to the aorta by way of suturing. For that purpose the wires contain loopholes or a series of circumferential notches (not shown) to enable suturing the wires to the aorta. The power cable **5** of the transducer is threaded through a hermetically sealed port in the housing **2** such that electrical energy may be delivered to the transducer from external source. The external end of the power cable ends with a connector **6** adequate for efficient connection to an external power source, e.g. BNC, UHF or a similar connector. The housing contains two ports **7** and **8**. Each of ports **7** and **8** is connected to one end of an external hose **9**. The combined housing and hose comprise a hermetically sealed closed volume. This combined volume is filled with a liquid, such as but not limited to degassed water, serving both as a coolant as well as a coupling medium to deliver acoustic energy from the transducer to the membrane. The ports may be designed such that the resistance to flow through port **7** is larger than the resistance to flow through port **8** so that residual positive

pressure will be maintained within the housing, which will inflate the membrane 3 and press it slightly against the insonated organ. The difference in flow resistance can be obtained for example by making the outlet port 7 narrower that inlet port 6.
The disposable transducer assembly depicted in Figure 3 above can be sterilized as is using standard sterilization methods, such as Gamma irradiation and then packed in a sterile envelope. The main problem to overcome is to keep the internal cooling liquid sterile during circulation such that if the membrane fails in operation and the liquid is spilled into the patient's chest cavity, sterility is not compromised. The solution to this problem is described below.

Figure 4 below depicts the connection of the disposable transducer assembly described above to the peripheral components, comprising the non-disposable components of the system:

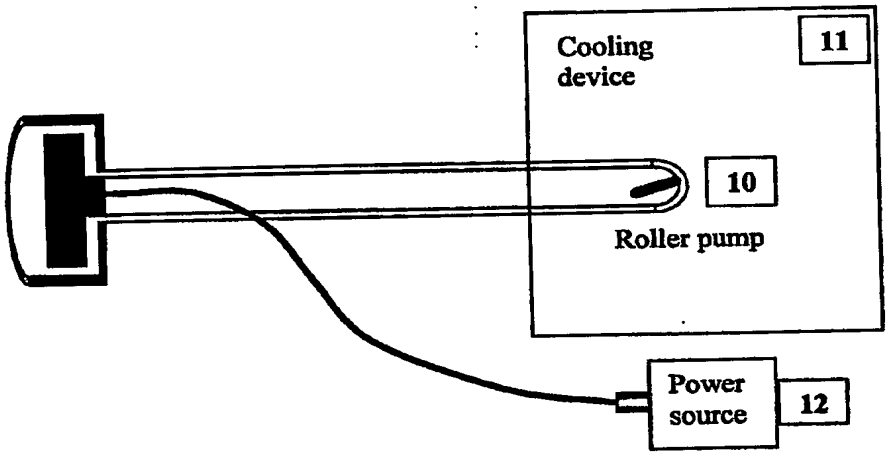

Figure 4 – Block diagram of the peripheral components

As is depicted in Figure 4 above the disposable transducer assembly is connected to two circuits – a power circuit and a coolant/liquid circuit. The external hose is connected to a roller pump **10**, which is capable to induce flow within the closed coolant/liquid circuit without contact with the liquid itself, maintaining the sterility of the liquid/coolant. The use of the roller pump or generally any other "non-contact" pump is therefore particularly useful in this context. Thus, even if the membrane breaks down and liquid/coolant is spilled into the patient, sterility is not compromised. Moreover, the external non-disposable roller-pump is not required to be sterile at all. The roller pump and the segment of the hose, connected to the roller pump, are maintained in a refrigerated compartment **11**, such that upon turning the roller-pump ON in coordination with activation of the transducer, a fresh supply of cold liquid to

the transducer housing enables maintaining the transducer within a desired temperature regime.
It may also be beneficial that the segment of the external hose, which is connected to the roller-pump, will have a larger diameter its part, connected to the transducer housing. This way the majority of the liquid/coolant will be maintained in the controlled temperature environment and easily supply cold liquid through the transducer housing for a long period of time.
The power cable is connected to the power supply unit **12**. In order to ensure disposability of the transducer assembly, the connector **6** (as depicted in Figure 3 above) may be equipped with internal chip or any other code-containing standard electronic element enabling the power supply unit to electronically control that every transducer assembly is used once.

Fixture the transducer housing to the aorta

The standard way to connect the transducer housing to the aorta of a patient undergoing a cardiac surgical procedure is depicted in Figure 5 below:

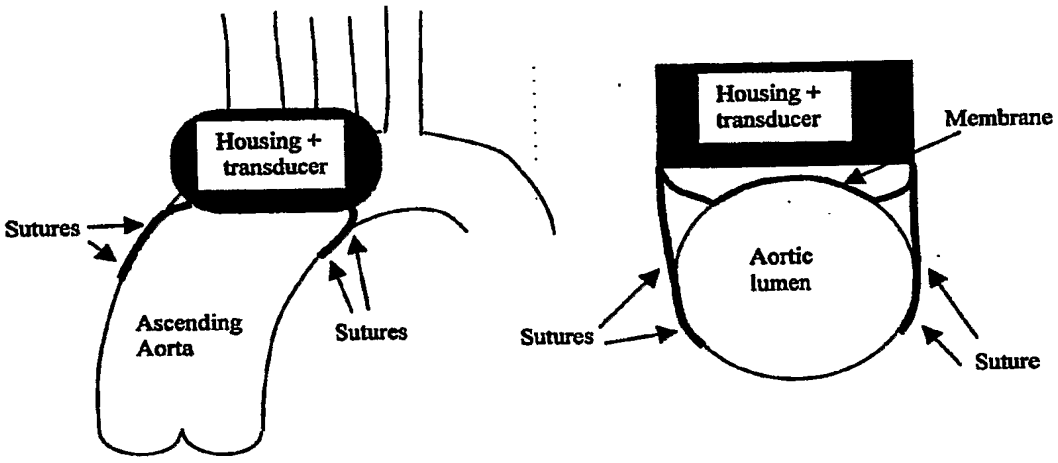

Figure 5 – Suturing the transducer housing to the aorta

The method to fix the transducer housing to the aorta is first to position the transducer housing in place and then bend the wires around the aorta and suturing them to the aorta (actually to the Adventitial layer which is the external layer of the aorta). The

most important advantage of this method is that the location of the transducer relative to the aorta will not change, even when the aorta moves, either by heartbeats or by any mechanical manipulation of the aorta by the surgeon. Thus, the acoustic beam will remain aligned at the origins of the innominate and left common carotid arteries. For enhanced stability of the transducer housing, the surgeon may suture the power cable, a few centimeters away from its connection to the transducers, to the patient's skin above the transducer housing.

Invention #3 – Method and system for gas cooling of ultrasonic transducer

Introduction:

Ultrasound energy for therapeutic applications is used in various medical scenarios such as destroying stones in the urinary system using sound shock waves (Lithotripter), high intensity focused ultrasound for ablation of malignant and benign tumors, ultrasound for acoustic management of embolism etc.

Any transducer intended to generate acoustic power for the use of therapeutic ultrasound may encounter the problem of heating of the transducer, or more specifically, its piezoelectric element, and the need for cooling the device in order to enable prolonged activation. Cooling of the transducer is usually achieved by immersing the transducer in controlled-temperature liquid (e.g. water) in order to remove excessive heat from the transducer. However, many power transducers utilize air-backing technology in which the piezoelectric element within the transducer is backed by air in order to prevent acoustic energy from flowing backwards and maintain high energy conversion efficiency. A typical air-backed transducer is depicted in Figure 6 below. As the piezoelectric element heats up in operation, even if the transducer is immersed in water, the cooling effect influences mainly the front side of the hot element. Its rear side is actually in contact with static air, which is a poor heat conductor. Moreover, piezoelectric elements are usually made of ceramic materials, which are poor heat conductors as well. Thus, the water removing heat from the front side of the piezoelectric element has little influence on the rear part of this element. Consequently, the temperature of the rear part of the element may increase and lead to its temporary or permanent malfunction. For this reason the acoustic energy generated by air-backed transducers is limited for thermal reasons (this limit varies between different types of piezoelectric element materials and their sensitivity to heat).

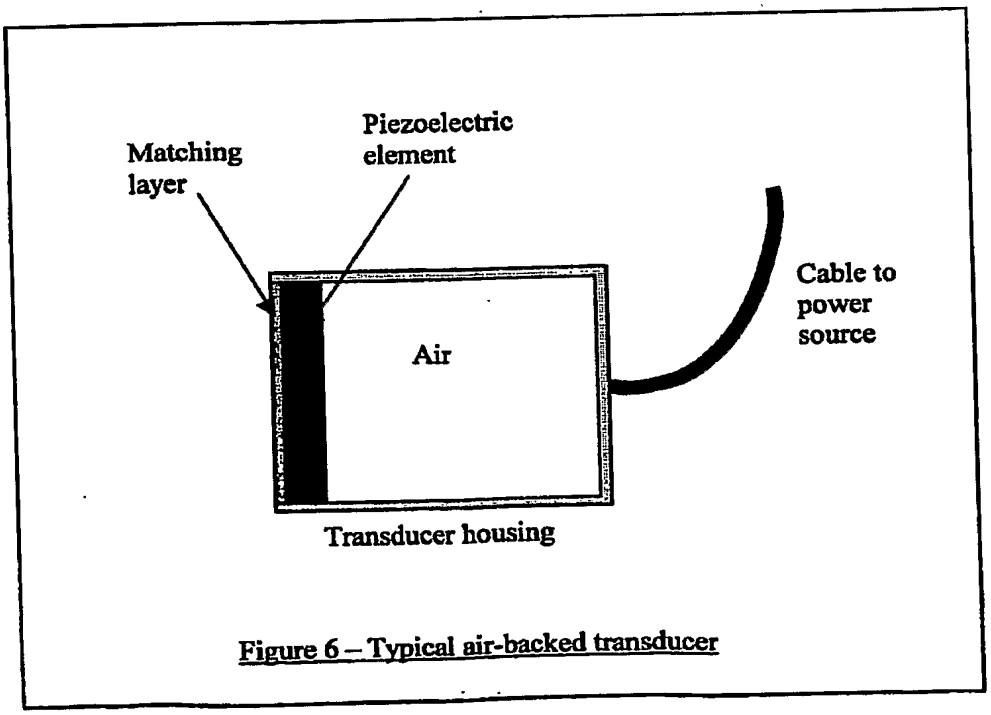

Figure 6 – Typical air-backed transducer

Description of the invention

The invention disclosed in this document is a system for gas-cooling an air-backed ultrasonic transducer, which provides a solution for the problem of overheating of air-backed ultrasonic sources and enabling the generation of higher acoustic power (or intensity) compared with standard air-backed transducers while not compromising the energy conversion efficiency.

Schematic descriptions of the disclosed embodiments are given in Figures 7, 8 and 9

Figure 7 depicts one embodiment of the disclosed invention which is based on an ultrasound producing element 4 such as but not limited to a piezoelectric element on the front which is housed in a hollow housing 5 made of any solid material such as but not limited to Aluminum, Titanium, Stainless steel etc. The ultrasound producing element is normally backed by gas (e.g. air). The cooling mechanism for the rear side of the ultrasound producing element is circulating gas 6. The gas enters the housing through an inlet 1 and leaves the housing through outlet 2. The cooling of the ultrasonic producing device by the gas can be done in several ways such as but not limited to insertion of compressed gas through a needle 3 which then de compresses and using the Joule-Thomson effect is cooled and therefore cools the gas in the housing and the back and sides of the ultrasound producing element.

Another yet not limiting method for cooling the gas is an external cooling device 7 (in Figure 8) that will cool the gas outside the housing and using a gas pump 8 will drive the cooled gas into the housing through the inlet 1 (See figure 8).

The gas running through the device can be both circulating in a closed loop, or with an open loop having an external gas source or pressure pump and having the gas leaving the outlet leave the system completely to the ambient environment.

Cooling by liquid + gas backing

Figure 9 depicts another invention embodiment which is based on an ultrasound producing element 4 such as but not limited to a piezoelectric element on the front which is housed in a hollow housing 5 made of any solid material such as but not limited to Aluminum, Titanium, Stainless steel etc. Yet in this case the ultrasound-producing element is not backed by gas but backed with another liquid and the liquid is backed by gas. The rear side of the liquid backing is made from an acoustically transparent material such as but not limited to Latex. The liquid back compartment has two ports (See figure 9), 9 is an inlet port connected to a liquid pump to allow flow of liquid into the housing and port 10 is an outlet port allowing liquid to flow from the housing back to the pump. The liquid used in this device can be water, degassed water or any other coolant used in the industry. This embodiment can be employed with or without gas cooling of the gas volume backing the back-liquid compartment.

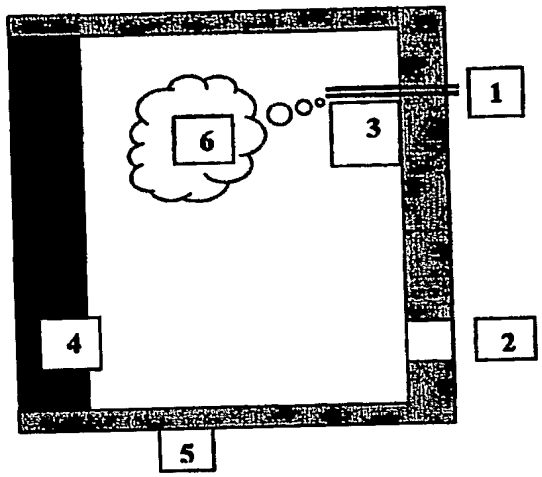

Figure 7 - Compressed gas cooling device

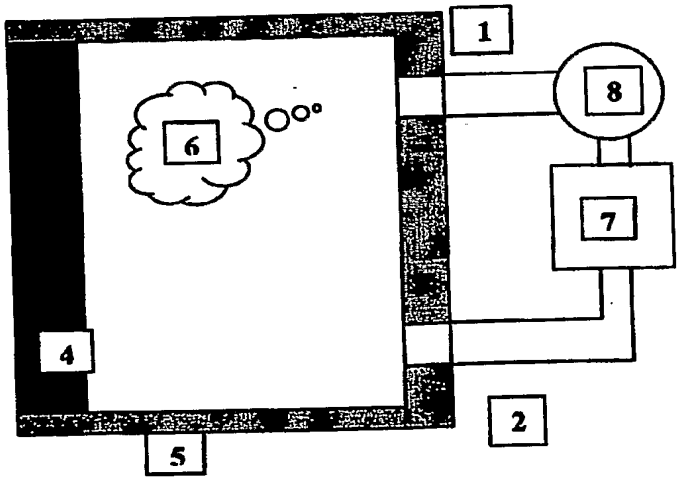

Figure 8 - Non-compressed cooled gas, cooling device

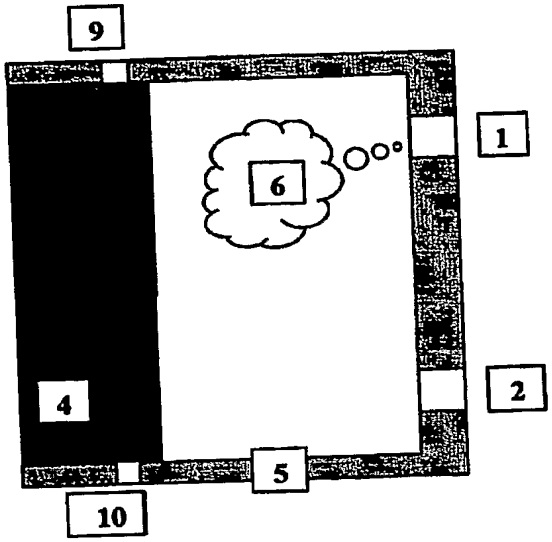

Figure 9 - Ultrasonic transducer cooled by both circulating liquid and gas.

Invention #4 – Method and system for acoustic emboli protection

Introduction

Methods and devices for elimination of cerebral emboli inside the human body via their diversion or blocking by acoustic forces and avoiding their passage to the brain have been described by MILO in a PCT application No. PCT/IB00/01785 and U.S. patent application 10/162,824, whose disclosures are incorporated herein by reference. The PCT application cited above teaches of various embodiments for diversion of intra-corporeal emboli using a variety of methods. One of the embodiments described therein is a "Collar" mounted around the neck of the patients, containing transducers pointing at the carotid bifurcation in order to block the passage of microbubbles and microparticles flowing in the common carotid arteries from entering the internal carotid arteries (leading to the brain) by causing them to flow into the external carotid arteries (supplying blood to the facial organs).

Summary of the invention

The invention disclosed in this disclosure is a method and system for blocking of embolic flow in the common carotid arteries from entering the internal carotid branches leading to the brain. The invention disclosed herein is designed as to become an integral part of closed chest procedures such as cardiological catheterizations, percutaneous cardiological interventions (PCIs) and minimally invasive cardiac surgical (MICS) procedures.

The major advantages of the proposed invention is:

- Simple and fast system deployment
- Simple operation
- Minimum ultrasonic energy imparted into the patient's body
- Reduced potential of thermal damage to patient
- Robust operation insensitive to reasonable variations in anatomy between patients

The concept

The concept of elimination of cerebral embolism suggested in this invention relies on a well-known effect in acoustical physics named "Acoustic Radiation Force" (ARF). The ARF effect states that an acoustic wave, traveling in an ambient liquid, exerts a net force on any particle residing in the fluid, provided that the acoustic properties of the particle (i.e. density and sound velocity) are different form those of the ambient fluid. Thus, utilizing the ARF one is able to exert forces on particles residing in a liquid without actually having to maintain physical contact with the particles. This is the basis for the concept presented here for elimination of cerebral embolism, presented in Figures 10 and 11 below:

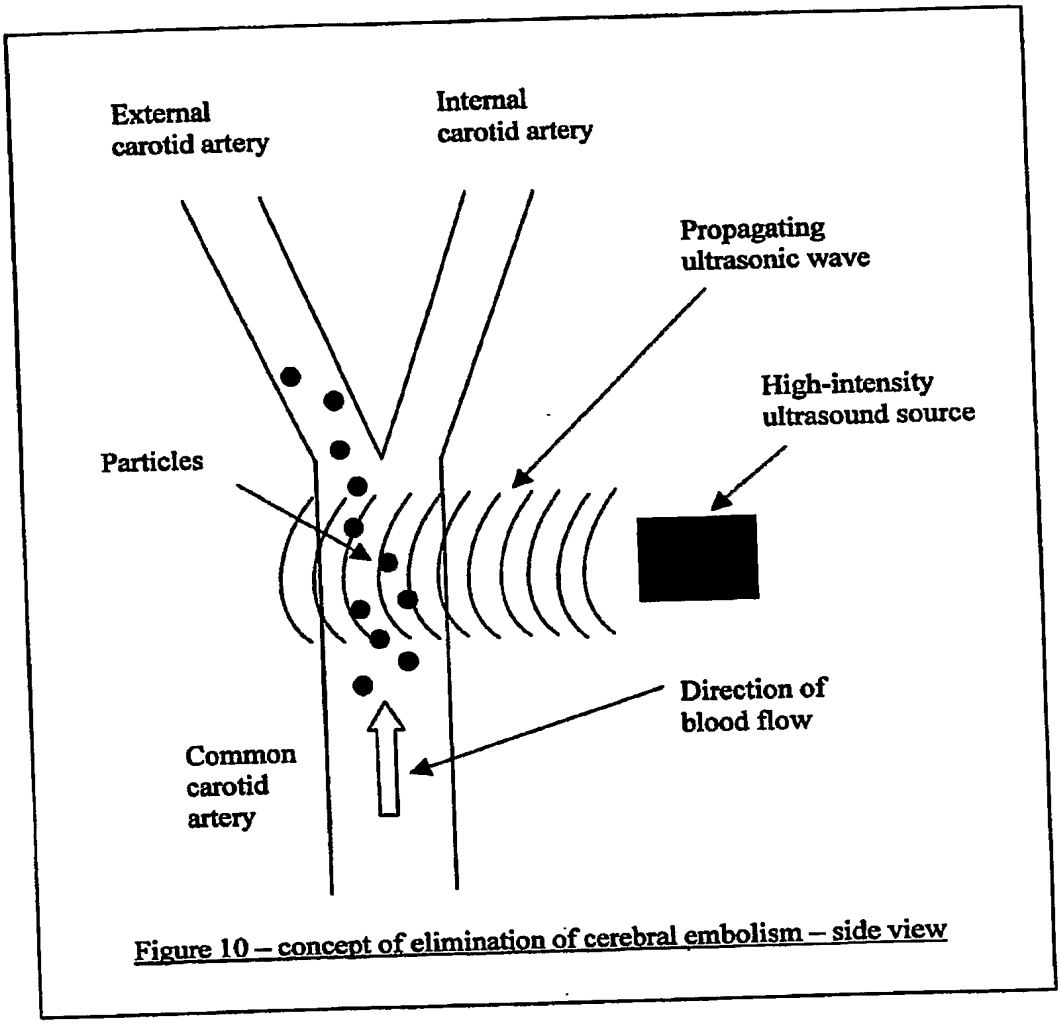

Figure 10 – concept of elimination of cerebral embolism – side view

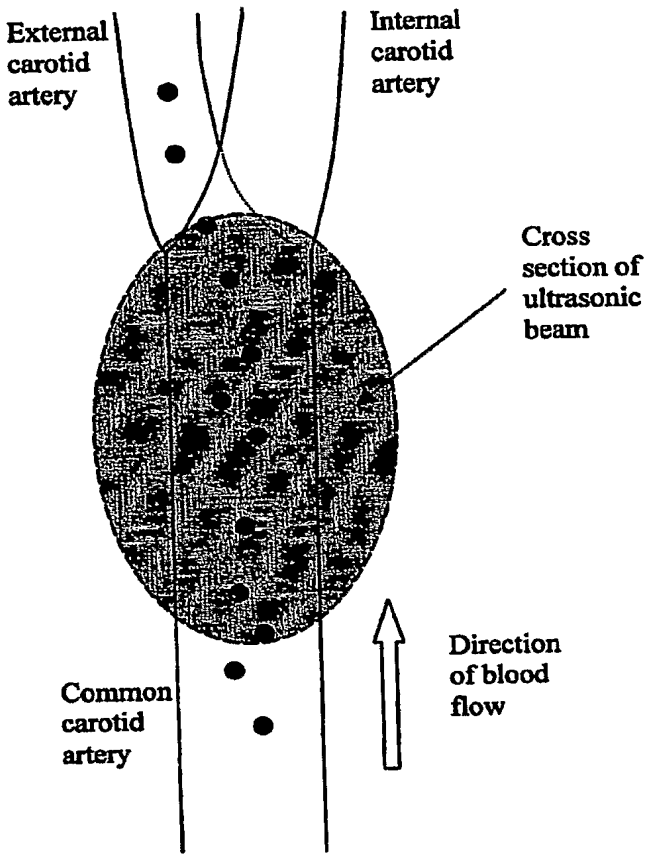

Figure 11 – concept of elimination of cerebral emboli – frontal view

The concept presented in Figures 10 and 11 is based on the specific nature of the arterial system supplying blood to the head through the neck. The majority of the blood is conveyed through the two common carotid arteries located on both sides of the esophagus. The common carotid arteries (CCA) originate in the aortic arch and bifurcate into the external carotid artery (ECA) and the internal carotid artery (ICA) slightly below the mandibular bone. The ICAs supply blood to the brain (and the eyes as well) and the ECAs supply blood to the facial organs. The main idea underlying the concept of elimination of cerebral emboli is directing an ultrasonic beam in a specific direction, so as to block passage of embolic flow from the CCAs into the ICAs, allowing the emboli to flow only into the ECAs.

Description of the invention

A general view of the disclosed invention and the deployment of the system is given in Figure 12 below:

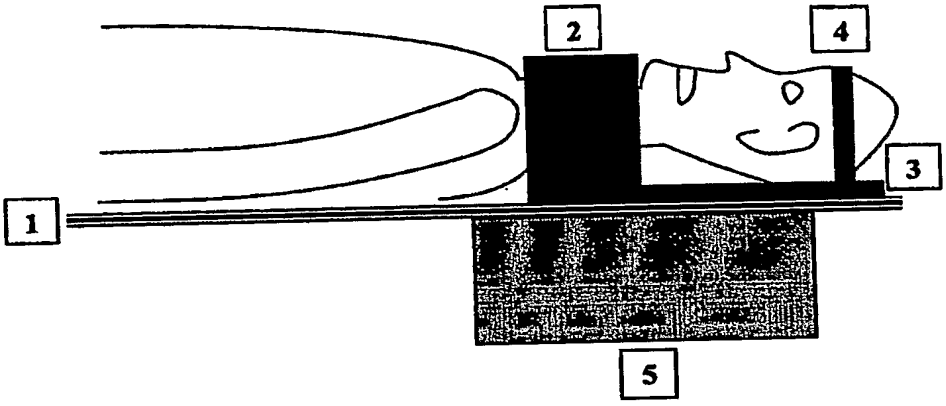

Figure 12 – General view of the invention

The system depicted in Figure 12 above may be integrated into the standard patient table, **1**, used in catheterization labs and cardiac surgical theaters. Above the table, **1**, are mounted all system components, which need to be in contact with the patients: The protection collar, **2**, which contain the power transducers, means for their mechanical manipulation and the acoustic matching components, a pad, **3**, allowing for a convenient and stable support to the patient's head and a belt or band, **4**, for stabilization of the patient's head and neck during the procedure.

A cross section of the protection collar **2** is given in Figure 13 below. The body of the collar **1** is made from a rigid material such as but not limited to metals like Stainless steel or polymers such as Perspex, Polycarbonate etc., contains a hollow inner cavity. The two power transducers **2** are mounted on both sides of the body of the collar. A liquid filled pad or cushion **3** is mounted in the hollow cavity of the body of the collar. The liquid-filled pad has a hollow central region covered with an acoustically matching gel layer **4** or similar coupling materials. The gel layer is covered with a protecting sheet made from paper or similar, to protect it when it is not used. This sheet is removed before operation, exposing a clean smooth surface of gel layer. The liquid-pad is connected to the exterior via two ports: inlet port **5** and outlet port **6**. The transducers are connected to external plugs **7** and **8**.

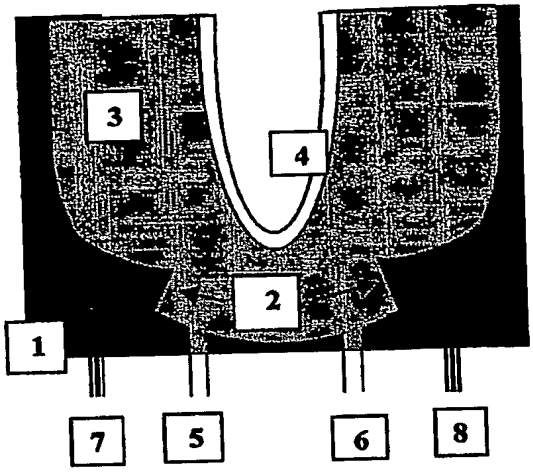

Figure 13 – Cross section of the Protection Collar

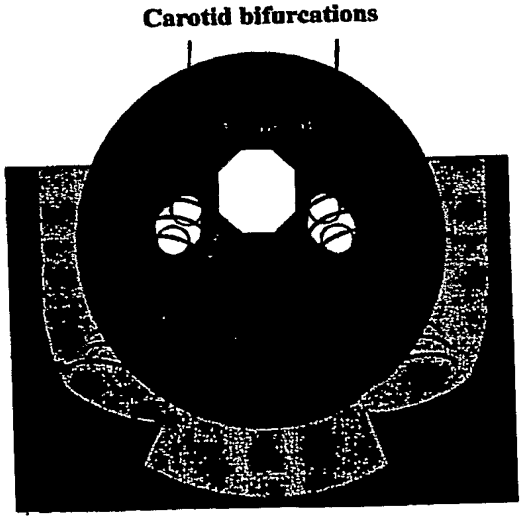

Figure 14 – Cross section of the protection collar around patient's neck

The deployment of the collar on the table is done by insertion of the electrical plugs 7 and 8 and the water inlet and outlet connectors 5 and 6 to appropriately designed sockets existing in the table and connected on their other side to the central command and control unit (# 5 in Figure 12 above).
The liquid inlet and outlet ports, may be connected to a pump and cooling device (which are not disposable) installed in the external command and control unit (similar concept to the previous inventions disclosed in this document).

Figure 14 above depicts the situation when the neck of the patients is positioned into the protection collar and the transducers are activated. The neck is pressed against the liquid-filled pad (cushion) and good acoustic coupling is obtained also via the acoustically matching gel (#4 in Figure 13). The transducers are designed in such a way as to generate a wide enough acoustic beam to compensate for typical variations in the anatomy of the carotid arteries and the carotid bifurcation. In the longitudinal direction (the direction pointing into the page in Figure 14) the transducers are long enough to cover the whole gap between the clavicular bones and the mandibular bone (typical around 10 cm) so that the whole length of the CCAs is insonated.

The collar itself may be designed to be disposable, such that when the neck of the patient is remove from the collar, the gel layer is deteriorated and cannot be used a second time.

In another embodiments of this invention, the transducers are mounted on mechanically controlled manipulators, which enable the surgeon or cardiologist to maneuver the transducers and change their position and orientation according to the specific anatomy of the patient. The correct positioning and alignment of the transducers can be done manually or automatically in conjunction with real-time imaging data obtained by standard imaging devices used in surgical theaters and cath labs, such as X-ray based fluoroscopy imaging used in cath labs, ultrasound imaging devices (such devices are used in cardiac surgery theaters for the purpose of aortic imaging), etc.

Detect-and-hit embodiment
If the ultrasound intensities required to achieve blocking of emboli from entering the ICA are higher than allowed or desired in CW operation, a different approach may be implemented. The suggested approach is based on keeping the power transducers idle for the most of the operation and activating them for a short period of time following the detection of particles or bubbles flowing in the CCA. For this purpose, Doppler transducers are incorporated in the protection collar. Such transducers are connected to an emboli detection system, such as a TCD (Transcranial Doppler device, intended for intra-cranial detection of emboli). This concept is based on the fact that typical number of emboli detected throughout the course of cardiac surgery is of the order of hundreds to a few thousand (in PCIs and cardiac catheterization this figure is significantly smaller, around 100 per procedure). The duration of such a procedure is 2 hours or more. Thus, taking a typical duration of 10,000 seconds, it follows that the emboli rate is usually smaller than 1 embolus/sec. However, the time required for an embolus to flow along the entire length of the CCA is of the order of a few tens of milliseconds. Thus, the high-power ultrasonic source does not have to be continuously operated during the whole procedure, but rather only intermittently, provided that means for emboli detection are employed. This method will allow the reduction of the

overall acoustic energy imparted to the patient's neck by a factor of 10 or more. The proposed embodiment is depicted in Figure 15 below:

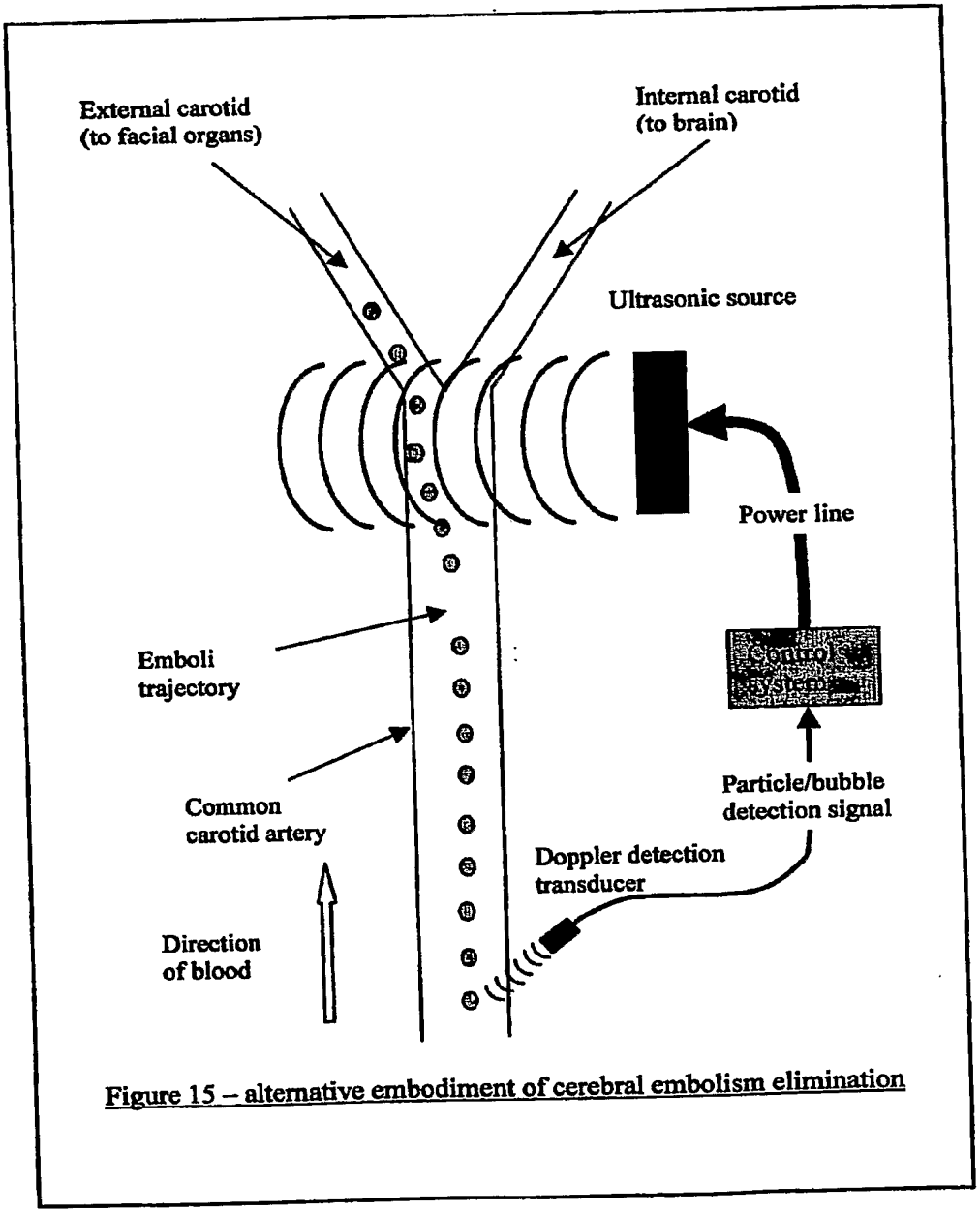

Figure 15 – alternative embodiment of cerebral embolism elimination

Invention #5 – Ultrasonic system and disposable sterile wave-guide assembly

Introduction

The inventions presented above require the introduction of an ultrasonic transducer in close proximity to the body under treatment in such a way that the insonated tissue within the body is positioned within the ultrasonic beam. This may pose problems such as the requirement of sterility of the transducer itself (e.g. in Invention #2 above) or geometrical constraints preventing the use of relatively large transducers in proximity to the body (e.g. in the Protective Collar embodiments the available space for the transducers behind the neck of the patient may be small). It is therefore desirable to position the transducer in a location where geometrical constraints and/or sterility considerations are irrelevant and to deliver the acoustic energy to the treatment site via a dedicated conduit.

Description of the invention

The invention disclosed herein is a method and device for conveying acoustic energy from the location of energy generation to the treatment site, through an acoustic wave-guide. A general description of the system is depicted in Figure 16 below:

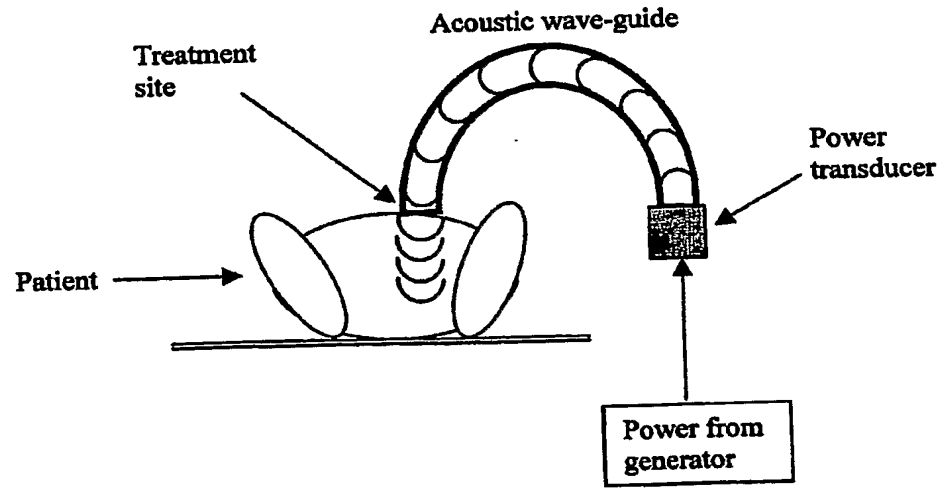

Figure 16 – General sketch of delivering therapeutic acoustic energy via a waveguide

A general structure of the acoustic wave-guide is given in Figure 17 below. It is based on a hollow confining shell 1, made from any flexible material that enables bending of the wave-guide without kinking or the like, such as thin polymer or metallic layer. This layer has to be very thin compared with the acoustic wavelength such that minimum acoustic energy will undergo mode conversion and deliver acoustic energy into the layer. The hollow space in the shell is filled with a coupling material which is liquid or solid flexible or polymer material, 2, having low acoustic attenuation, such as but not limited to degassed water or acoustic gel. Preferably, to minimize reflection of energy from the treated body, the coupling material possesses acoustical properties matched to water or living tissue. In the case that the coupling material is liquid, both ends of the wave-guide are covered with thin membranes, 3, enabling good acoustic coupling to the transducer on one end and to the body on the other hand. A schematic drawing of the wave-guide is given in Figure 17 below (not to scale):

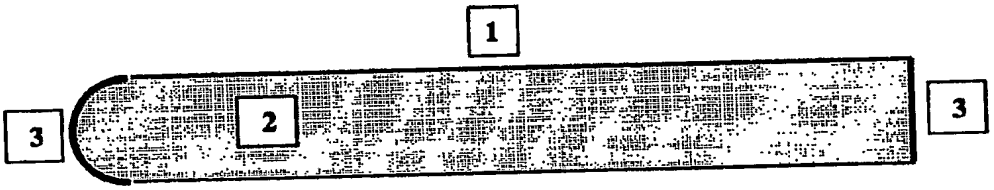

Figure 17 – A schematic description of the wave-guide

The wave-guide may be filled with a constant quantity of liquid coupler or it may be connected to an external liquid circulating system comprising a pump and a cooling device, so as to constantly replenish the liquid inside the wave-guide. (similar to embodiment disclosed above).

An improved design of a wave-guide may be one incorporating an internal acoustic lens. Such a design is useful in cases in which the application constraints require the wave-guide to be of small diameter but still provide a wide acoustic beam at the point of application of the acoustic energy. For example if the acoustic energy needs to be delivered to the aortic arch during cardiac surgery (this application is disclosed in provisional application no. 60/544,459 filed February 12, 2004) then the wave-guide itself must have a small diameter in order to minimize interference in the surgical field but still provide a wide acoustic beam to the aortic arch This problem may be resolved by installing an acoustic divergent lens at the distal side of the wave-guide (i.e. close to the point of contact with the body of the patient). This is depicted in Figure 18 below:

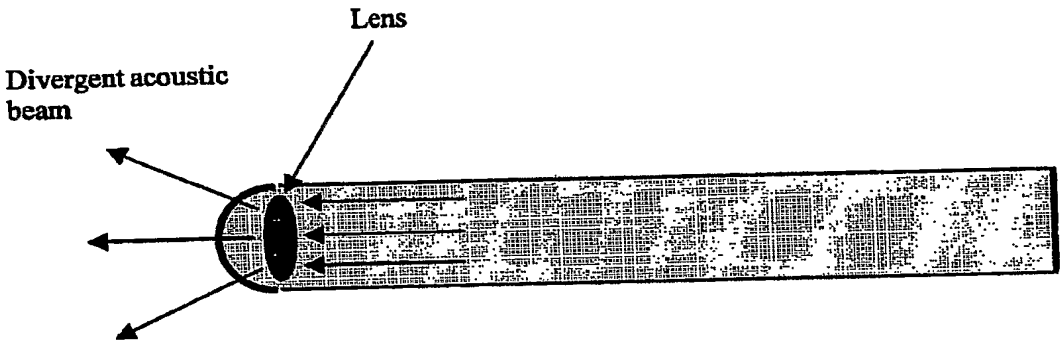

Figure 18 – An acoustic wave-guide with acoustic lens

It should be emphasized that the shape of the lens is a function of the required divergence (or convergence) and the respective acoustic properties of the coupling liquid and those of the lens material. The shape of lens depicted in Figure 18 has no specific meaning and it is symbolically drawn as is common in optics. This shape should not be considered as limiting the scope of this invention in any respect.

The optimal material for the lens should be such that on one hand it will possess different sound velocity from that of the coupling liquid so as to enable refraction which is the basis for lens theory and on the other hand it will possess acoustic impedance (product of density and sound velocity) as close as possible to that of the coupling liquid so as to minimize backward reflection of acoustic energy.

The wave-guide disclosed above may be also used in the Collar invention (Invention #4 above) in to avoid integrating the power transducers inside the collar and relieve tough geometrical requirements from such transducers.

Invention #6 – System and method of eliminating cerebral emboli

Introduction

The Protection Collar invention disclosed above (Invention #4) is intended to provide cerebral protection against emboli created upstream of the bifurcation of the common carotid artery (CCA) to the internal and external carotid arteries (ICA and ECA). This protection device does not generally provide cerebral protection against emboli, which are created in the ICA (downstream of the bifurcation). This is relevant mainly in Carotid artery angioplasty/stenting procedures in which the vast majority of lesions are within the bifurcation itself or even downstream in the ICA. In those cases the majority of emboli are created in the vicinity of the lesion.

Description of the invention

The invention disclosed below is an application of acoustic radiation force in order to block the flow of embolic material, which is already in the carotid bifurcation or even in the ICA and to push it upstream in order to transfer the embolic material into the CCA. There by virtue of the radiation force, blocking passage of the embolic material into the ICA, the embolic material will flow into the ECA, thus preventing neurological injury. This concept is depicted in Figure 19 below:

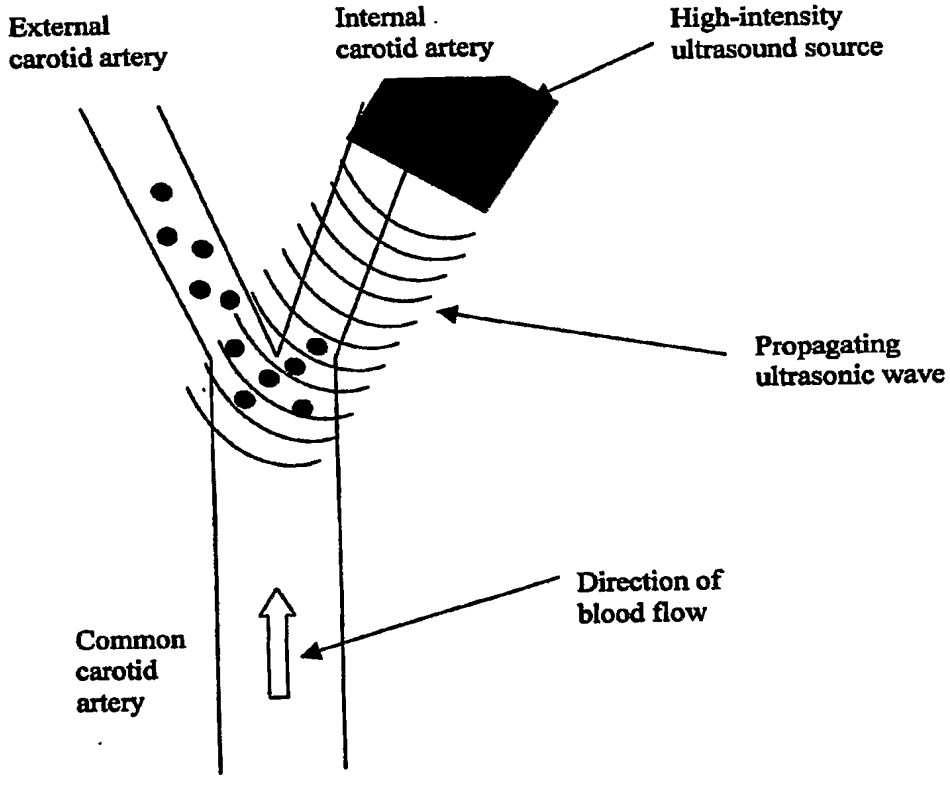

Figure 19 – Concept of blocking embolic material already in the ICA

It is clear from Figure 19 above that in order to accomplish blocking of embolic flow in the ICA and transfer it back to the CCA one needs to generate an acoustic beam approximately in parallel with the ICA. (In contrast with Invention #4 above where in order to prevent embolic flow in the CCA from entering the ICA the acoustic beam was perpendicular to the CCA). This is realizable in 4 possible embodiments:

Direct positioning of an ultrasonic transducer in proximity to the carotid bifurcation
This is the simplest realization of this invention and is actually depicted in Figure 19 above. The typical gap between the carotid bifurcation and the mandibular bone is of the order of 3-5cm. Thus, a transducer may be positioned in parallel with the exterior surface of the neck, such that its acoustic beam will cover the ICA and the bifurcation in a direction approximately parallel to the ICA.

Beam alignment using a phased array transducer
In order to avoid potential difficulty arising from tough geometrical constraints on transducers that need to be positioned in parallel to the ICA, a phased array technology may be utilized. Phased array transducers are capable of generating acoustic beams whose direction is electronically changed and controlled. This way one can conveniently position the ultrasonic transducers in the vicinity of the patient's neck away from the mandibular bone and steer the beam electronically to the desired angle, preferably approximately parallel to the ICA. See Figure 20 below:

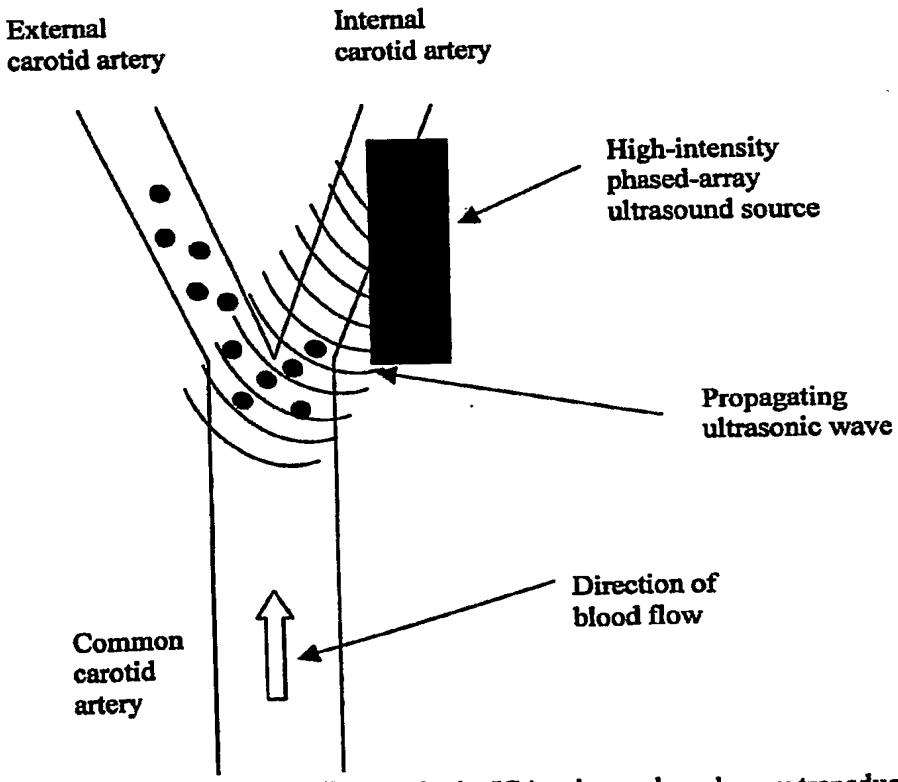

Figure 20 – Blocking embolic flow in the ICA using a phased array transducer

Beam alignment using an acoustic mirror

In this embodiment the transducer is not necessarily positioned adjacent to the patient's neck but rather in a more convenient position, while an acoustic mirror is utilized to achieve the desired beam orientation via reflection. Such acoustic beams are known in the literature and can be made of any material whose acoustic impedance is much very high, such as but not limited to metals, or very low, such as air or vacuum. In addition, the surface of the acoustic mirror should be very smooth in order to avoid dispersion of acoustic energy. See Figure 21 below:

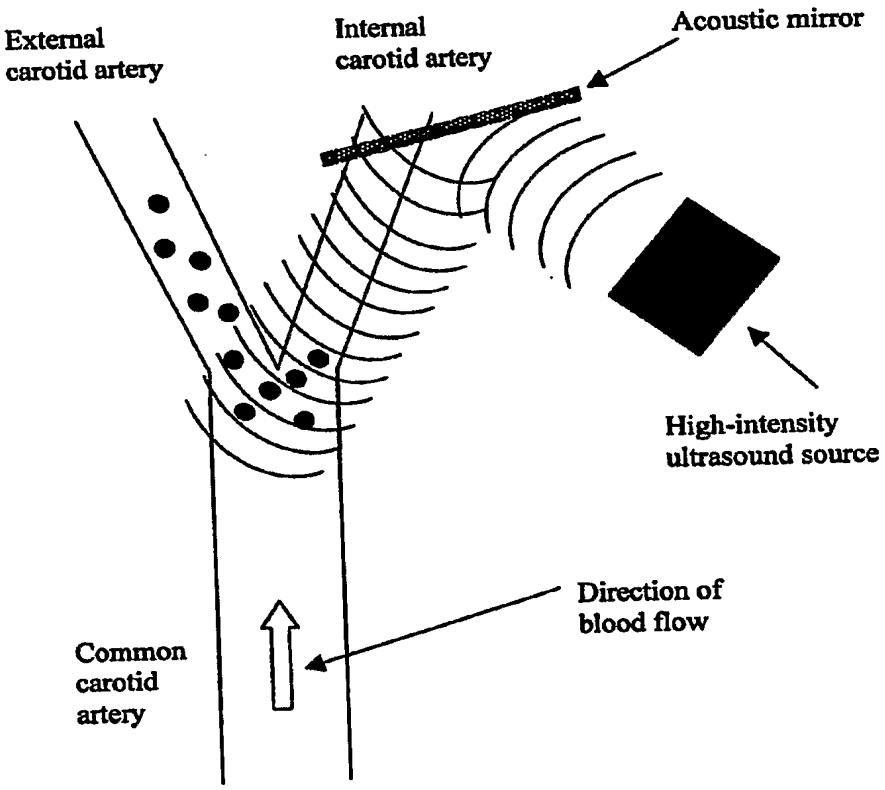

Figure 21 – Blocking of embolic flow in the ICA using an acoustic mirror

Beam alignment using an acoustic wave-guide
This embodiment is a combination of inventions #4 and #5 above, wherein the desired orientation of the acoustic beam with respect to the carotid artery is achieved by a waveguide. See Figure 22 below:

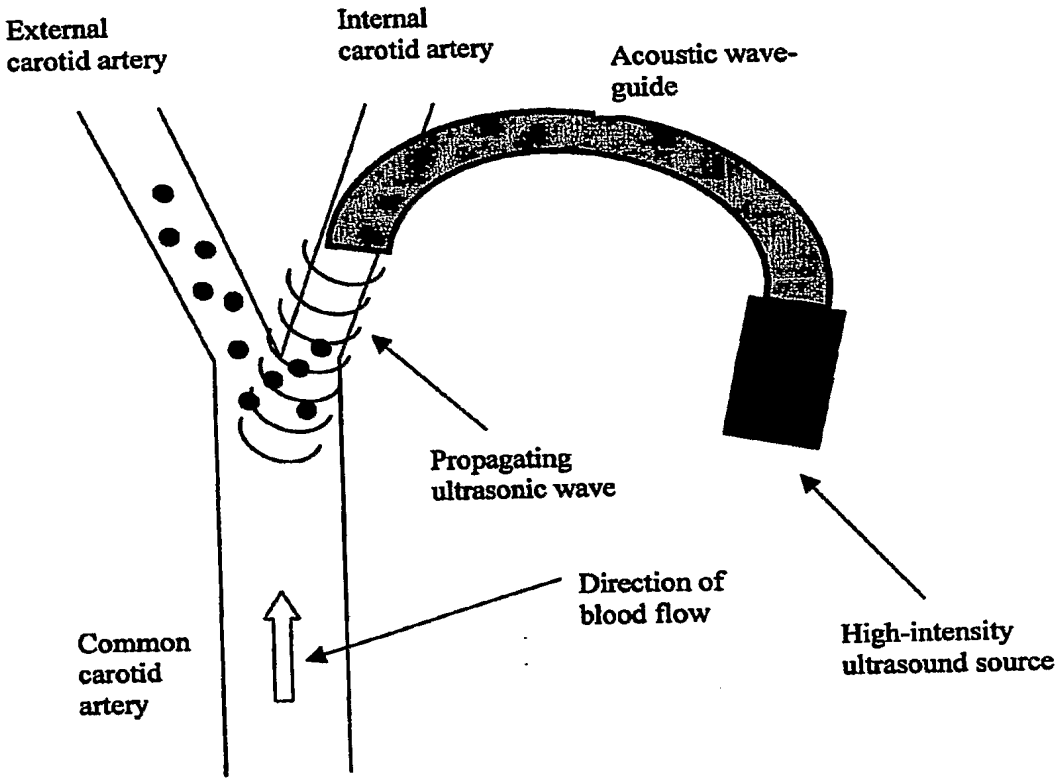

Figure 22 – Blocking embolic flow in the ICA using a wave-guide

All the above methods of delivery of an appropriate acoustic beam to impinge on the ICA and carotid bifurcation in the proper orientation are realizable within a Collar mounted around the neck of the patient, containing the different components disclosed above, whether transducers, wave-guides, mirror etc. All solutions described in Invention #4 above, such as Collar structure, acoustic coupling, disposability, etc., are directly applicable to this Invention #6.

The correct positioning and alignment of the acoustic beam with respect to the carotid bifurcation and the ICA can be done using guidance of standard imaging devices existing in the Cath Lab such as X-ray based fluoroscopy.